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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,581	12/21/2000	Therese Jourdier	00,1287	1597

7590 08/11/2004

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/746,581	Applicant(s) JOURDIER ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-5 and 8-10.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: The amended claims read on methods of inducing both a systemic and local immune response whereas the claims had previously required only the production of a local immune response.

Continuation of 5. does NOT place the application in condition for allowance because:

The Applicant presents three new arguments in response to the rejection of claims 1-3, 5, and 8-10 over Thibodeau in view of Lowell and Heiber. Additional arguments have been presented with respect to the induction of a systemic immune response. However, prior to the After-Final amendment, there was no requirement that the administration of the antigen to the floor of the mouth induce both a local and systemic immune response. Because the proposed amendment to the claims requires additional examination with respect to the new limitation, these amendments have not been entered. The arguments pertaining to these amendments have therefore also not been considered.

The Applicant first asserts that the Examiner has not even alleged that the art teaches the use of the claimed methods with respect to the genus of pathogens disclosed in the claims. However, it is noted that the Thibodeau reference is concerned with the induction of an immune response against HIV, and that the reference itself precludes its teachings with the statement "the principal way by which infectious agents gain access to an organism is through mucosal membranes." Thus, it would have been apparent to those in the art that the teachings of the references would be applicable against the pathogens indicated in the claims.

The Applicant's second argument presented with respect to this first ground of rejection is that the Thibodeau reference does not teach, inherently or otherwise, the administration of antigen to the floor of the mouth. While this may be the case, the argument is based on the teachings of a single reference where the rejection is based on the cumulative teachings of multiple references. Such arguments are not sufficient to overcome the rejection.

Third, the Applicant argues that there is no suggestion in the art to administer particularly to the floor of the mouth. However, Heiber does suggest that the floor of the mouth may be used, and there are no teachings in the cited references, or supplied by the Applicant, to teach away from this route of administration. Further, the Applicant has not demonstrated that administration by this route is superior to administrations by alternative routes.

The Applicant also argues (fourth argument) that none of the cited references teach "targeting the buccal mucosa...by administration not to the buccal mucosa, but to the floor of the mouth." However, because the art cited suggests the administration of antigens to the floor of the mouth, the art would inherently result in the induction of an immune response in the buccal membranes. Further, according to the art (see e.g., Kozlowski et al., Infection and Immunity 65:1387-94, page 1387) teaches that it is "a well-documented fact that administration of antigen to one mucosal region may generate S-IgA antibodies at distant mucosal sites." Thus, those in the art would have had a reasonable expectation that induction of an immune response in the floor of the mouth would also result in the same in the buccal membrane.

The Applicant's last traversal is a restatement of the argument that there is no ground for applying the results in rabbits with reference to rabbits to humans. This argument is not found persuasive for the reasons indicated in the prior action. The unsupported statement in the Declaration is not sufficient to demonstrate that those in the art would not have expected the same route of administration to work in humans, particularly in light of the clear indications to the contrary found in the art.

This rejection is therefore maintained.

The Applicant traverses the rejection over claims 1-3, 5, and 8-10 over Thibodeau in view of Mathiowitz, Heiber, Lowell, and Irwin on the grounds that Mathiowitz does not specifically teach the administration of the immunogen to the floor of the mouth, and that Irwin does not suggest that the lymph nodes could be targeted by the oral administration to the oral mucosal surfaces. These rejections are not found persuasive. It is first noted that the rejection, as asserted by Applicant, is not merely over the teachings of Thibodeau in view of Mathiowitz and Irwin. The rejection was clearly restated in the prior action to teach the claimed invention through inclusion of the Lowell and Heiber references. In view of this, the Applicant's first argument is not found persuasive. The Applicant's second argument is not found persuasive for the reasons indicated in response to the Applicant's fourth argument in traversal of the rejection above.

The Applicant's traversal of the next rejection is based on the pathogen targeted, and the inclusion of the limitation regarding to systemic responses. The first argument is not found persuasive for the reasons indicated above. The second argument is not considered as the new limitation has not been entered into the application.

The Applicant traverses the rejection of claims 1-3, 5, and 8-10 over the Hinkula in view of Irwin, Beckenkamp, Kozlowski, and Gorse on two grounds. First, the Applicant argues that the references do not teach the induction of a mucosal response in the claimed method against pathogens "with a gateway into the buccal membrane region." However, the Kozlowski reference states "secretory IgA play an important role as a first line of defense against microorganisms that infect via mucosal surfaces." The reference continues by teaching the induction of immune responses in mucosa spread to nearby lymph nodes, and through to other mucosal surfaces. Thus, it would have been obvious to those in the art to use this method in the induction of an immune response against any pathogen that infects the subject through any mucosal surface. This argument in traversal is therefore not found persuasive. The second argument, that "none of the teachings suggest the floor of the mouth specifically" is not found persuasive in view of the teachings in Beckenkamp indicating that the floor of the mouth was able to induce the production of a secretory immune response. While the other may indicate that other routes may be more effective, this is not a teaching away from such administration.

Finally, the Applicant traverses the rejection over claims 1-5, 8-10 over Becker in view of Gorse and Beckenkamp on the grounds that the references cannot be said to teach either the targeting of the specific genus of pathogens identified in the claims, or the administration to the floor of the mouth. The first rejection is not found persuasive because, among the pathogens identified as falling within the scope of the claims is HIV, and in particular the claims teach the use of the gp160 antigen of HIV. Such an antigen is disclosed in Becker. Thus, the reference inherently teaches the claimed limitation. The second ground of rejection is not found persuasive in view of the teachings of Beckenkamp as described above.


For the reasons above, and of record, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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